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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,156	11/02/1999	GLAUCIA PARANHOS-BACCALA	103514	2490

25944 7590 09/25/2003

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/25/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/319,156

Applicant(s)

PARANHOS-BACCALA ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-9,13-17 and 25-64 is/are pending in the application.
- 4a) Of the above claim(s) 2,13,16,17,25,26,31-34,39-43 and 52-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-9, 14, 15, 27-30, 35-38, 44-51, and 60-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 60/2
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the communication filed 25 June, 2003. Claims 3-6, 10-12, and 18-24 were canceled without prejudice or disclaimer, claims 1, 2, 7-9, 13-17, 25, and 26 amended, and new claims 27-64 submitted. Claims 1, 7-9, 14, 15, 27-30, 35-38, 44-51, and 60-64 are currently under examination. Newly submitted claims 31-34, 39-43, and 52-59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly proposed claims are directed toward structurally and functionally distinct retroviral nucleic acids. Applicants are reminded of the original restriction requirement clearly set forth in paper no. 9 and the election of nucleic acids encoding the Env as set forth in paper no. 10. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-34, 39-43, and 52-59 are withdrawn from further consideration as being directed towards a nonelected invention (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03). This application contains claims 2, 13, 16, 17, 25, 26, 31-34, 39-43, and 52-59 drawn to an invention non-elected. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01).

35 U.S.C. § 112, Second Paragraph

2. Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reference to a gene which begins in one SEQ ID NO.

and ends in a different SEQ ID NO. in claim 8 is confusing. Applicants should clearly identify the nucleotide sequence of the claimed region. For instance, an isolated and purified nucleic acid comprising SEQ ID No.: X. Applicants' response fails to
5 address this deficiency.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most
15 nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 7-9, 14, 15, 27-30, 35-38, 44-51, and 60-64 are rejected under 35 U.S.C. § 112, first paragraph, as containing
20 subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d
25 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935
30 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of nucleic acids (e.g., equivalent sequences, sequences with a certain degree of homology, and fragments thereof). An applicant shows possession of the
35 claimed invention by describing the claimed invention with all of

its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or

partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The specification describes the isolation and characterization of a novel human retrovirus that may be associated with multiple sclerosis. A molecular clone was obtained and the purported nucleotide sequence of the env gene ascertained. Thus, the skilled artisan would reasonably conclude that applicants were in possession of those particular clones containing SEQ ID NOs.: 6, 9, and 12. Appropriately drafted claim language directed toward these embodiments would be acceptable. However, the broadly recited

claim language directed toward fragments, equivalents, and homologous sequences is unacceptable. Upon perusing the specification, nothing would lead the skilled artisan to any one of these particular sequences. None of these sequences are described in any detail. Accordingly, the skilled artisan would reasonably claim that applicants were not in possession of all these other sundry sequences.

Applicants traverse and submit that the disclosure provides a sufficient written description for the claimed invention. This argument is not persuasive for the reasons immediately set forth supra. Nothing in the disclosure directs the skilled artisan to the large genus of nucleotide sequences currently being claimed. Applicants are advised to direct the claim language toward those embodiments receiving direct support in the disclosure.

Finality of Office Action

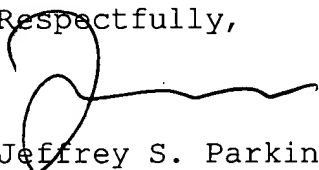
5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

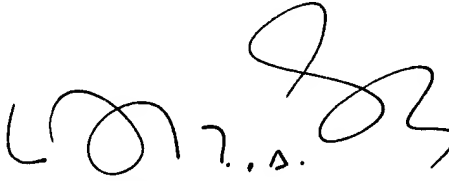
6. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers

5 must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
directed toward the following Group 1600 fax number: (703) 872-
9306. Any inquiry concerning this communication should be directed
to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-
2227. The examiner can normally be reached Monday through Thursday
from 8:30 AM to 6:00 PM. A message may be left on the examiner's
voice mail service. If attempts to reach the examiner are
unsuccessful, the examiner's supervisors, Laurie Scheiner or James
10 Housel, can be reached at (703) 308-1122 or (703) 308-4027,
respectively. Any inquiry of a general nature or relating to the
status of this application should be directed to the Group 1600
receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

20 September, 2003


LAURIE SCHEINER
PRIMARY EXAMINER